

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

DAIICHI SANKYO, INC., AND DAIICHI
SANKYO CO., LTD., : : Civil Action No. 03-0937 (SDW-MCA)

Plaintiff/Counter-Defendants, : : **OPINION**

v. : : May 18, 2009

APOTEX, INC. AND APOTEX CORP., : :

Defendants/Counter-Plaintiffs. : : : :

Daiichi Sankyo, Inc. and Daiichi Sankyo Co., Ltd. (collectively “Daiichi”) filed this patent infringement case against Apotex, Inc. and Apotex Corp. (collectively “Apotex”) in March, 2003. Apotex filed a series of defenses and counterclaims alleging that the patent was invalid or unenforceable. After discovery and a trial, this Court held that Apotex had infringed Daiichi’s patent and dismissed Apotex’s counterclaims that the patent was invalid or unenforceable. The Federal Circuit reversed on the grounds that the patent was invalid as obvious. Before the Court is Plaintiff/Counter-Defendant Daiichi’s Motion to Dismiss, pursuant to Fed. R. Civ. P. 12(b)(6), Apotex’s remaining counterclaims for monopolization in violation of the Sherman Act § 2, attempted monopolization, tortious interference with a prospective business relation, and unjust enrichment.

This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1337 and 28 U.S.C. § 1331, and supplemental jurisdiction over Apotex’s state-law claims under 28 U.S.C. § 1337. Venue is proper pursuant to 28 U.S.C. § 1391(b).

I. Factual Background and Procedural History¹

Daiichi filed the current case against Apotex in March, 2003, alleging patent infringement relating to Apotex's attempt to market a generic version of ofloxacin antibiotic ear drops for which Daiichi held U.S. Patent No. 5,401,741 (the "'741 patent"). The '741 patent is actually a "method for treating bacterial ear infections by topically administering the antibiotic known as ofloxacin into the ear." 441 F. Supp. 2d at 676.

With its Answer, Apotex brought several counterclaims including invalidity, anticipation, obviousness, unenforceability due to inequitable conduct, noninfringement, and misuse. Apotex also filed counterclaims alleging monopolization in violation of the Sherman Act § 2, attempted monopolization, tortious interference with a prospective business relation, and two others which were later withdrawn.

In September, 2004, Magistrate Judge Arleo severed Apotex's original counterclaims for monopolization, attempted monopolization, tortious interference with a prospective business relation, and the two subsequently withdrawn claims. Proceedings regarding the severed counts were stayed pending trial. However, Apotex's remaining counterclaims—including invalidity, anticipation, obviousness, unenforceability due to inequitable conduct, noninfringement, and misuse—were not stayed. Discovery on each of these issues was extensive, lasting almost two years. During the discovery period, Apotex deposed numerous Daiichi witnesses including the inventors of the '741 patent and Daiichi's patent prosecution counsel.

A 9-day trial was held before Judge Bassler in November, 2005. During the trial, Apotex presented its allegations that Daiichi engaged in inequitable conduct before the United States Patent and Trademark Office ("PTO"). Specifically, Apotex attempted to show that Daiichi had

¹ A full recitation of the facts and earlier procedural history can be found in Judge Bassler's opinion of August 2, 2006, *Daiichi v. Apotex*, 441 F. Supp. 2d 672 (D.N.J. 2006).

committed fraud in its application for the '741 patent by making material misrepresentations to the PTO and by failing to disclose prior art.

In a detailed written opinion dated August 2, 2006, Judge Bassler held that Apotex had infringed on Daiichi's patent and that Daiichi had not engaged in inequitable conduct. Judge Bassler based the findings of fact on "careful consideration of the testimony adduced at trial and a review of the documentary evidence submitted, as well as the logical inferences to be drawn from them." *Daiichi*, 441 F. Supp. 2d at 675. The Opinion also makes clear that "[i]n evaluating the evidence of record, the Court undertook an individualized assessment of the credibility of each witness and assigned the appropriate weight to the testimony based on the Court's conclusions with respect to credibility." *Id.*

An appeal followed. On September 12, 2007, the United States Court of Appeals for the Federal Circuit reversed, holding that the patent was invalid as obvious.² The Court stated that "[b]ecause we hold the '741 patent invalid as obvious, we need not reach Apotex's arguments that the '741 patent was anticipated or procured through inequitable conduct." *Daiichi v. Apotex*, 501 F.3d 1254, 1259 n.5. (Fed. Cir. 2007).

Apotex filed amended counterclaims on July 8, 2008, alleging (1) Monopolization in violation of the Sherman Act § 2 based on Daiichi's alleged fraud before the Patent and Trademark Office; (2) attempt to Monopolize in violation of the Sherman Act § 2; (3) tortious interference with a prospective business relation; and (4) unjust enrichment. Daiichi filed the

² The Federal Circuit held that Judge Bassler erred when he defined the ordinary person skilled in the art related to the '741 patent "would have a medical degree, experience treating patients with ear infections, and knowledge of pharmacology and use of antibiotics. This person would be . . . a pediatrician or general practitioner-those doctors who are often the 'fist line of defense' in treating ear infections." *Daiichi v. Apotex*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). Instead, the Federal Circuit held that "the level of ordinary skill in the art of the '741 patent is that of a person engaged in developing pharmaceutical formulations and treatment methods for the ear or a specialist in ear treatments such as an otologist, otolaryngologist, or otorhinolaryngologist who also has training in pharmaceutical formulations. Thus, the district court clearly erred in finding otherwise." *Id.* at 1257.

current motion to dismiss all counterclaims on September 5, 2008. Oral argument was held on April 29, 2009.

II. Standard for Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6)

In considering a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the Court must “accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.” *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008). (quoting *Pinker v. Roche Holdings Ltd.*, 292 F.3d 361, 374 n.7 (3d Cir. 2002)). As the Supreme Court has explained:

While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the “grounds” of his “entitle[ment] to relief” requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level.

Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 127 S. Ct. 1955, 1965 (2007) (internal citations omitted). In *Phillips*, the Third Circuit carefully considered the Supreme Court's holding in *Twombly* and stated:

The Supreme Court's *Twombly* formulation of the pleading standard can be summed up thus: “stating . . . a claim requires a complaint with enough factual matter (taken as true) to suggest” the required element. This “does not impose a probability requirement at the pleading stage,” but instead “simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of” the necessary element.

Phillips, 515 F.3d at 234 (quoting *Twombly*, 127 S. Ct. 1955).

III. Discussion

A. Judge's Bassler's Opinion Regarding Inequitable Conduct

Daiichi argues that all of the counterclaims are based on the same factual allegations of fraud and misrepresentation underlying Apotex's inequitable conduct defense. Because Judge Bassler concluded there was no inequitable conduct—a conclusion that was not overturned on appeal—Daiichi argues that the law of the case doctrine dictates dismissal of Apotex's counterclaims. Apotex argues that the law of the case does not preclude reconsideration of Judge Bassler's opinion because its counterclaims were stayed (and hence never considered) and because the Federal Circuit did not reach the merits of the inequitable conduct issue on appeal. In considering these arguments, it is helpful to compare Apotex's allegations that formed the basis of its inequitable conduct counterclaims, which were decided after full discovery and a trial, with its current counterclaims, which were stayed.

Apotex's monopolization, tortious interference, and unjust enrichment counterclaims are based primarily on Daiichi's conduct before the PTO in connection with two other patents: the published German patent application DE 36 32 222 A1 to Grohe ("Grohe '222"), and the Hirota patent 4,923,862 ("Hirota '862"). The same conduct related to these two patents formed the basis for Apotex's inequitable conduct counterclaim, which was presented at trial.

1) Grohe '222

Apotex's defense of inequitable conduct alleged that during the course of the '741 Patent application process, Daiichi made false representations to the PTO related to the Grohe '222 application.

Applicants for the '741 patent represented to the PTO in that Form PTO-1449 and Information Disclosure Statement that the '222 application does not disclose or suggest that the solutions can be applied to the external auditory canal or injected intratympanically. Contrary to that representation, the '222 Application, at page 31, line

12 of the translation, lists the use of the topical ofloxacin preparations of the invention in the treatment of, *inter alia*, otitis in dogs.

(Plfs.’ Answer ¶ 56.) An almost identical allegation is made in connection with Apotex’s monopolization claim. (Defs’ Amended Counterclaim ¶ 54 (hereinafter “Counterclaim”).)

Apotex also alleged that Daiichi engaged in inequitable conduct in the ’741 patent application process by falsely listing the effective date of the Grohe ’222 application.

Applicants for the ’741 patent represented to the PTO in that Form PTO-1449 and Information Disclosure Statement that the date of the ’222 application was “07/07/88”, after the effective filing date of the ’741 patent. Contrary to that representation, the ’222 application was published April 7, 1988, before the effective filing date of the ’741 patent.

(Answer ¶ 55.) This allegation is also a foundation of Apotex’s monopolization claim. (See Counterclaim ¶ 51.)

Judge Bassler engaged in a detailed analysis of these allegations, and stated he was “not persuaded that Daiichi’s statements about the Grohe patent application constitute false representations, which were intended to deceive the patent examiner.” 441 F. Supp. 2d at 692. In addition, the Court did “not find that there is clear and convincing evidence that Daiichi intended to mislead the examiner by typing the incorrect date on the IDS.” *Id.* The Court also noted that Apotex had not presented “clear and convincing evidence that the typed incorrect date was anything more than a typographical error.” *Id.*

2) Hirota ’862

Apotex’s inequitable conduct defense and its monopolization counterclaims are also both based on the allegation that Daiichi “did not discuss, or disclose to the PTO, U.S. Patent No. 4,923,862; U.S. Patent No. 4,382,892; and/or U.S. Patent No. 5,053,407.” (Amended Answer ¶ 59; Counterclaim ¶ 57.) Apotex alleged, and continues to allege, that these patents are “material prior art to the ’741 patent” and should have been disclosed. (Answer ¶ 58; Counterclaim ¶ 56.)

It is also alleged that these patents were assigned to Daiichi, who should have been aware of their existence. (Answer ¶57; Counterclaim ¶ 55.) Judge Bassler flatly rejected these allegations, concluding that “Apotex has presented no clear and convincing evidence to show that Daiichi intentionally failed to disclose the Hirota patent.” 441 F. Supp. 2d at 693. The Court also noted that “Daiichi voluntarily submitted an IDS for the Hirota patent application. Although no one could find the document in the file history, Apotex has put forth no evidence that the absence of the document is a result of Daiichi's wrongdoing.” *Id.*

In addition to the allegations of fraud related to Grohe '222 and Hirota '862, Apotex alleges two additional bases for its counterclaims: (1) Listing the '741 patent in the FDA's “Orange Book” knowing it was obtained through “fraud and/or inequitable conduct”; and (2) Bringing the current patent enforcement claim knowing the patent had been obtained through “fraud and/or inequitable conduct.” As addressed more fully below, these claims are dependant on the same allegedly fraudulent conduct before the PTO.

B. Immunity From Suit for Antitrust Violations

The *Noerr-Pennington* Doctrine generally provides immunity from antitrust liability for a party who petitions the government for redress. *See Eastern R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965). In the patent context, this immunity can be overcome by (1) demonstrating that the patent infringement litigation brought by the patentee is a sham, *Professional Real Estate Investors v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 57–58 (1993); or (2) the patent holder “obtained the patent by knowingly and willfully misrepresenting facts to the Patent Office,” *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965). The latter is

commonly referred to as “*Walker Process* fraud.” Because Apotex does not plead or argue that Daiichi engaged in “sham litigation,” it is not addressed here.

1) Walker-Process Fraud

The affirmative defense of inequitable conduct and a *Walker Process* counterclaim, “share common factual elements.” *Cabinet Vision v. Cabinetware*, 129 F.3d 595, 600 (Fed. Cir. 1997); *Celgene Corp. v. Barr Laboratories, Inc.*, 07-cv-286 (SDW), 2008 WL 2447354, at *2 (D.N.J. June 13, 2008) (noting that inequitable conduct and *Walker Process* fraud “both rely on factual allegations of misrepresentation to the PTO during the patent application process”). However, The Federal Circuit has “distinguished ‘inequitable conduct’ from *Walker Process* fraud, noting that inequitable conduct is a broader, more inclusive concept than the common law fraud needed to support a *Walker Process* counterclaim.” *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069 (Fed. Cir. 1998). Indeed, “[a] finding of inequitable conduct does not by itself suffice to support a finding of *Walker Process* fraud.” *Dippin’ Dots, Inc. v. Mosey, et al.*, 476 F.3d 1337, 1346 (Fed. Cir. 2007).

A patent may be unenforceable for inequitable conduct when the application for the patent “with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution.”” *Id.* at 1345 (quoting *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006). In analyzing a claim for inequitable conduct, intent to deceive “must generally be inferred from the facts and circumstances surrounding the applicant's overall conduct.” *Id.* at 1345 (quoting *Paragon Podiatry Lab., Inc. v. KLM Labs, Inc.*, 984 F.2d 1182, 1189 (Fed. Cir. 1993). In contrast, *Walker Process* fraud requires a showing of *actual fraud* on the PTO, as well as the other elements required for a Sherman Act § 2 claim. *Dippin’ Dots*, 476 F.3d at 1346 (quoting

Walker Process, 382 U.S. at 175). The question of whether an applicant committed a fraud on the PTO is governed by Federal Circuit Law. *Id.*

The Federal Circuit has explained the difference between the showings required for inequitable conduct and *Walker Process* fraud as follows:

A finding of *Walker Process* fraud requires higher threshold showings of both intent and materiality than does a finding of inequitable conduct. Moreover, unlike a finding of inequitable conduct, a finding of *Walker Process* fraud may not be based upon an equitable balancing of lesser degrees of materiality and intent. Rather, it must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance, *i.e.*, that the patent would not have issued but for the misrepresentation or omission. Therefore, for an omission such as a failure to cite a piece of prior art to support a finding of *Walker Process* fraud, the withholding of the reference must show evidence of fraudulent intent. A mere failure to cite a reference to the PTO will not suffice.

Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1070–71 (Fed. Cir. 1998) (citations omitted); *see Dippin' Dots*, 476 F.3d at 1347 (noting that ‘[t]he difference in breadth between inequitable conduct and *Walker Process* fraud admits the possibility of a close case whose facts reach the level of inequitable conduct, but not of fraud before the PTO’).

If a finding of inequitable conduct may be insufficient to meet the more rigorous standard for *Walker Process* fraud, it logically follows that *Walker Process* fraud can not be found in the absence of inequitable conduct. *See FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1417 (Fed. Cir. 1987) (noting that “failure to establish inequitable conduct precludes a determination that [plaintiff] had borne its greater burden of establishing the fraud required to support its *Walker Process* claim.”). Such is the case here. Judge Bassler found that Daiichi had not engaged in inequitable conduct. As addressed more fully below, this Court sees no reason—and Apotex has not provided one—to disturb that finding.

C. The Law of the Case Doctrine

Apotex argues that because the Federal Circuit expressly did not reach the question of whether Daiichi had engaged in inequitable conduct before the PTO, Judge Bassler's decision is not the law of the case and this court may reconsider its findings. Daiichi contends that under the law of the case doctrine, this Court may not revisit Judge Bassler's determination that they did not engage in inequitable conduct. As addressed above, if the finding of no inequitable conduct stands, there can be no *Walker Process* fraud and Apotex's antitrust counterclaims should be dismissed.

“The law of the case doctrine ‘limits relitigation of an issue once it has been decided’ in an earlier stage of the same litigation.” *Hamilton v. Leavy* 322 F.3d 776, 786–787 (3d Cir. 2003); *In re Continental Airlines, Inc.* 279 F.3d 226, 233 (3d Cir. 2002) (the law of the case doctrine stands for the proposition that “when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case” (quoting *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816 (1988))). The doctrine is designed to “promote finality, consistency, and judicial economy.” *Hamilton*, 322 F.3d at 786. As the Third Circuit has explained:

The law of the case doctrine does not limit a federal court’s power; rather, it directs its exercise of discretion “A court has the power to revisit prior decisions of its own or of a coordinate court in any circumstance, although as a rule courts should be loathe to do so in the absence of extraordinary circumstances such as where the initial decision was ‘clearly erroneous and would work a manifest injustice.’” This Circuit has recognized several “extraordinary circumstances” that warrant a court’s reconsideration of an issue decided earlier in the course of litigation. They include situations in which: (1) new evidence is available; (2) a supervening new law has been announced; or (3) the earlier decision was clearly erroneous and would create manifest injustice.

Public Interest Research Group of N.J., Inc. v. Magnesium Elektron, Inc., 123 F.3d 111, 116 - 117 (3d Cir. 1997) (quoting *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800

(1988) (citations omitted). Apotex has not argued that any of these exceptions apply. Instead, it argues that because the Federal Circuit reversed and explicitly declined to address the inequitable conduct issue, Judge Bassler's decision on that issue cannot be the law of the case.

At oral argument, counsel for Apotex put a slightly finer point on this argument. Counsel stated that the Federal Circuit reversed the *entire* Judgment of the District Court, including its determination of inequitable conduct. *See Daiichi*, 501 F.3d at 1259 (holding that "the judgment of the District Court is Reversed"). Part of the District Court's Judgment was "entered in favor of Daiichi and Against Apotex on all of Apotex's affirmative defenses and counterclaims I-VI alleging noninfringement, invalidity or unenforceability." Judgment ¶ 4, Aug. 2, 2006, Docket No. 188. At oral argument, counsel for Apotex argued that because the Federal Circuit reversed *the Judgment* of the District Court, nothing in Judge Bassler's opinion survives. Hence, the argument goes, the Court's findings related to inequitable conduct cannot be the law of the case. Counsel for Apotex said, "[i]t's the judgment we're looking at. . . . [A]ll of those findings of fact of Judge Bassler are all to support the judgment. [If] [t]he judgment fails, those findings are useless. They mean nothing. . . . So they're not the law of the case." (Hr'g Tr. 18:21–25, April 29, 2009.) This court disagrees. The Federal Circuit opinion makes absolutely clear that its basis for reversing the Judgment was that "the invention of the '741 patent would have been obvious to one having ordinary skill in the art at the time of the invention. The Court was also clear that it did "not reach Apotex's arguments that the '741 patent was anticipated or procured through inequitable conduct." *Daiichi v. Apotex*, 501 F.3d 1254, 1259 n.5. (Fed. Cir. 2007).

In support of its argument, Apotex relies in part on *Exxon Corp. v. U.S.*, 931 F.2d 874 (Fed. Cir. 1991). In that case, the Court explained that the "[l]aw of the case . . . merely requires a trial court to follow the rulings of an appellate court." *Id.* at 877. There is no question that

this Court is bound by the Federal Circuit's decision that the '741 patent was obvious. This is often referred to as the "mandate rule." "Under the mandate rule, a species of the law of the case doctrine, 'a trial court must comply strictly with the mandate directed to it by the reviewing court.'" *Skretvedt v. E.I. DuPont De Nemours* 372 F.3d 193, 203 n.13 (3d Cir. 2004) (quoting *Ratay v. Lincoln Nat. Life Ins. Co.*, 405 F.2d 286, 288 (3d Cir.1968)).³ However, the law of the case controls prior decisions of this Court that were not addressed by the Federal Circuit.

When a court of appeals reverses a judgment and remands for further consideration of a particular issue, leaving other determinations of the trial court intact, *the unreversed determinations of the trial court normally continue to work an estoppel.* . . . When the estoppel is operative in proceedings in the same case on remand, courts frequently speak in terms of the law of the mandate or the law of the case rather than collateral estoppel but the underlying principle is the same.

Cowgill v. Raymark Industries, Inc., 832 F.2d 798, 802 (3d Cir. 1987) (citing 1B J. Moore, J. Lucas & T. Currier, *Moore's Federal Practice* ¶ 30.416[2], 517 (3d ed. 1984)) (emphasis added). As the Court in *Exxon* explained, the law of the case doctrine "does not constrain the trial court with respect to issues not actually considered by an appellate court." *Exxon Corp.*, 931 F.2d at 877. In this case, the Federal Circuit explicitly stated it did not reach the inequitable conduct arguments. Although Apotex is correct that the Federal Circuit's mandate reversed and did not remand the case for further consideration, the principles of the law of the case doctrine still apply to "direct" this Court's "exercise of discretion" and counsel against re-visiting Judge Bassler's

³ As another District Court in this Circuit has explained:

Appellate courts often remand a case to the lower federal courts for further proceedings. It is often stated that the decision of an appellate court on an issue of law becomes the law of the case on remand. This is the almost universal language describing the law determined by the mandate. Although this terminology has been widely adopted, the Supreme Court has noted that the mandate rule is not, strictly speaking, a matter of law of the case

Rozzelle v. Rossi, No. 98-cv-1738, 2007 WL 2905728, at *1, (W.D.Pa., Sept. 30, 2007) (quoting 18-134 *Moore's Federal Practice-Civil* § 134.23).

finding that Daiichi did not engage in inequitable conduct. *See Public Interest Research Group*, 123 F.3d at 116–17. This is particularly true because of the fact-intensive nature of that finding. “If an attempt is made to press the same fact issue for a second time on an unchanged record, law-of-the-case reluctance approaches maximum force. This view may be taken with respect to mixed issues that blend fact with legal appraisal.” Charles Alan Wright, Arthur R. Miller, & Edward H. Cooper, 18B Federal Practice and Procedure Proc. §4478.5 (2d ed. 2009).

Judge Bassler presided over nine days of trial and wrote a detailed opinion addressing the specific facts alleged to have amounted to inequitable conduct—the same facts that form the basis of Apotex’s counterclaims. Judge Bassler determined that Daiichi had not engaged in inequitable conduct after careful consideration of a full factual record. This Court declines to revisit that decision. To do so would be to annihilate the critical values of “finality, consistency, and judicial economy” that the law of the case doctrine is designed to protect. *See Hamilton*, 322 F.3d at 786. Apotex has not argued that new facts, or an intervening change in law, warrant reconsideration of Judge Bassler’s decision on inequitable conduct. To hold that the Federal Circuit’s reversal eviscerates the inequitable conduct portion of that decision—even though it *expressly* declined to reach it—exceeds the bounds of reason. Accordingly, Apotex cannot demonstrate *Walker Process* fraud and its monopolization claims must be dismissed as a matter of law.

D. Listing the ’741 Patent in the FDA “Orange Book”

Apotex alleges that Daiichi listed the ’714 patent in the FDA “Orange Book” “with the full knowledge that [the patent] was obtained by fraud and/or inequitable conduct” (Counterclaim ¶ 61) and that such listing was “objectively baseless” (*Id.* ¶ 66). The Hatch-Waxman Act, 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e), establishes a procedure for

manufacturers of brand-name pharmaceuticals to provide notice of all claimed patents to generic manufacturers. It also creates a process for a brand-name manufacturer to address a potential patent infringement when a generic manufacturer seeks FDA approval to market a generic version of a brand-name drug. The FDA publishes a book titled the “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly referred to as the “Orange Book”), which contains all the patents claimed by the manufacturers of FDA-approved drugs.

Apotex argues that “Daiichi’s listing of a fraudulently-obtained patent provides a separate basis for Apotex’s monopolization and attempt to monopolize counterclaims.” (Defs.’ Opp’n Br. 18.) More specifically, Apotex argues that its monopolization claims must survive Daiichi’s motion because they are based in part on Daiichi’s listing the ’741 patent in the FDA’s Orange Book knowing it was obtained through “fraud and/or inequitable conduct.” Apotex also argues that Daiichi’s listing of the ’741 patent in the Orange Book is not subject to *Noerr-Pennington* immunity. *See, e.g., Organon Inc. v. Mylan Pharms., Inc.*, 293 F. Supp. 2d 453, 457 (D.N.J. 2003); *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 369–75 (S.D.N.Y. 2002). We need not determine whether such immunity applies because as alleged in Apotex’s counterclaim, the Orange Book listing was only wrongful if the patent was obtained through fraud or was “objectively baseless”. Judge Bassler’s decision makes patently clear that it was not. The same is true for the claim that Daiichi filed this patent infringement action knowing that the patent was obtained through fraud. Both allegations are based on the instances of fraud before the PTO, which Judge Bassler expressly rejected. With no fraud, the subsequent Orange Book listing and lawsuit were not wrongful and cannot form an independent basis for Apotex’s counterclaims.

E. Apotex's State Law Counterclaims

State law tort claims are preempted by federal law if they are based on nothing more than misconduct before the PTO. *See Semiconductor Energy Laboratory Co., Ltd. v. Samsung Electronics Co., Ltd.*, 204 F.3d 1368, 1382 (Fed. Cir. 2000). Apotex's counterclaim for tortious interference with a prospective business relation is based on two primary facts: Daiichi's listing of the '741 patent in the Orange Book and its bringing this patent infringement suit, both with the knowledge that the patent had been obtained by fraud. (Counterclaim ¶¶ 103–104). Apotex claims these actions were “objectively baseless and done in bad faith.” (*Id.* 104.) Apotex's unjust enrichment claim is based on exactly the same facts. (see Counterclaim ¶¶ 110.) As addressed above, both counterclaims are, at the core, based on the same alleged fraudulent conduct before the PTO. Without the alleged fraud, no liability could attach to Daiichi's listing the '741 patent in the Orange Book or it's filing of this infringement action. Accordingly, both are preempted by Federal Law. *See In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F.Supp.2d 514, 546 (E.D.N.Y. 2005) (noting that Plaintiffs' claim that a patent was improperly listed in the Orange Book depended “on a showing that the . . . [p]atent was obtained by fraud on the PTO. Plaintiffs cannot by this collateral or backdoor method avoid preemption of their state law claim”).⁴

IV. Conclusion

This Court is loathe to overturn Judge Bassler's determination that Daiichi had not engaged in inequitable conduct before the PTO through specific instances of misleading or fraudulent conduct. Because that same conduct forms the foundation of all of Apotex's counterclaims, those counterclaims are DISMISSED with prejudice.

⁴ Apotex argues that Delaware Law should apply to its unjust enrichment claim. Because this claim is preempted regardless of which state's law applies, it is unnecessary to undertake a choice of law analysis.

SO ORDERED.

s/ Susan D. Wigenton, U.S.D.J.

cc: Magistrate Judge Madeline C. Arleo